EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
Media and Reagent Preparation: Assigning Prep and Sterilization Run Numbers

SOP Number: QC-15-02

Date Revised: 08-28-02

Prepared By: _____ Date: ___/___/___

Print Name:_____

Reviewed By: _____ Date: ___/___/___

Print Name:_____
Technical Staff

_____ Date: ___/___/___

Print Name:_____
QA Officer

_____ Date: ___/___/___

Print Name:_____
Laboratory Director

Date Issued: ___/___/___

Withdrawn By: _____ Date: ___/___/___

Controlled Copy No.: _____

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1.0 SCOPE AND APPLICATION:

1.1 This protocol describes the procedures used to assign media/reagent preparation and sterilization batch control numbers. Tracking media and reagents from preparation to use must be thoroughly documented.

2.0 DEFINITIONS: None

3.0 HEALTH AND SAFETY: Not applicable

4.0 CAUTIONS: None

5.0 INTERFERENCES:

5.1 The suffix on all preparations is critical for the tracking of all preparations and its assignment must be made by following the SOP explicitly.

6.0 PERSONNEL QUALIFICATIONS:

6.1 Personnel must be knowledgeable of the procedures for assigning preparation and sterilization batch control numbers. Documentation of training and familiarization with this SOP can be found in the training file for each employee.

7.0 SPECIAL APPARATUS AND MATERIALS: None

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable

9.0 SAMPLE HANDLING AND STORAGE:

9.1 Media and reagents are subject to proper storage as specified by the manufacturer.

10.0 PROCEDURE AND ANALYSIS:

10.1 When preparing media and reagents, completion of the Media/Reagent Preparation Sheet and Performance Log Form is required (see 16.0).

10.2 All media and reagents will be assigned a preparation control number. The preparation control number consists of two parts: 1) the first seven

digits represent the date the media or reagent was prepared: PMMDDYY where P=Prepared, MM=month, DD=day, and YY=the last two digits of the calendar year; and 2) the suffix, where the digits after the dash act as a counter for the number of preparations made on the same date. For example, the first preparation made on April 29, 1999 would have the control number P042999-01. The next item prepared on that same day would have a suffix of -02; the third preparation made on that same day would have a suffix of -03; etc.

10.3 For all media and reagents that are sterilized by autoclaving, a sterilization batch number is assigned. The procedure for assigning the sterilization batch number follows similar notation for assigning preparation control numbers. The sterilization batch number consists of two parts: 1) the first seven digits represent the date the batch was sterilized: SMMDDYY where S=Sterilization, MM=month, DD=day, and YY=the last two digits of the calendar year; and 2) the suffix where the first digit after the dash indicates the autoclaved used and the next two digits act as a counter for the number of preparations made on the same date. For example, the first batch sterilized on April 29, 1999 in autoclave 1 (rm B206) would have the control number S042999-101. The next batch sterilized on that same day and same autoclave would have a suffix of -102; the third batch sterilized would have a suffix of -103; etc. (autoclave 1=B206, autoclave 2=B204, autoclave 3=B207 autoclave 4=B202).

10.4 The Media/Reagent Preparation sheet identifies information relevant to the preparation of the media or reagent. The preparation sheet may also be used for non-media items that require a preparation control number such as glass slide carriers, porcelain carriers, and steel carriers.

10.5 All boxes on the Media/Reagent Preparation sheet must be filled out with the appropriate information for that section. If a section is not applicable to the item being prepared, place NA (Not Applicable) in that section.

10.6 Record the storage requirement for the media at the bottom of the page. If the material is to be used immediately and requires no storage, then place NA in that section.

11.0 DATA ANALYSIS/CALCULATIONS: None

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 Data will be recorded promptly, legibly, and in indelible ink on the appropriate forms. Completed forms are archived in notebooks kept in locked file cabinets in the file room D217. Only authorized personnel have access to the locked files. Archived data is subject to OPP's official retention schedule contained in SOP ADM-03, Records and Archives.

13.0 QUALITY CONTROL:

13.1 The OPP Microbiology Laboratory conforms to 40 CFR Part 160, Good Laboratory Practices. Appropriate quality control measures are integrated into each SOP.

13.2 For quality control purposes, the required information is documented on the appropriate form(s) (see 16.0).

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 If a preparation control number or sterilization batch number is missing and cannot be determined from the Media/Reagent Preparation Sheet (see 16.1) or the Daily Sterilization Record Information Log Form (see 16.2), the media or reagent will not be used in any testing procedure and will be discarded.

15.0 REFERENCES: None

16.0 FORMS AND DATA SHEETS:

16.1 Media/Reagent Preparation Sheet

16.2 Media/Reagent Preparation and Performance Log Form

16.3 Daily Sterilization Record Information Log Form

Media/Reagent Preparation Sheet
OPP Microbiology Laboratory

Media/Reagent Name:	
Amount Prepared:	Preparation Date/Initials:
Prep #:	Sterilization Number:

Media/Chemical Ingredients:	Control No:	Amount Required:	Amount Weighed:

Preparation/Modifications/Notes:

Required pH:	Original pH:	Final pH: Temperature:

Volume of Acid/Base added to obtain final pH:	

Sterility/Viability Test Results	Sterility		Viability	
	Pass	Fail	Pass	Fail

Storage of Reagent/Media:

Media/Reagent Preparation and Performance Log Form

OPP Microbiology Laboratory

Media Information				Sterility	Record the date that the information is entered, P = pass, F = Fail, NR= none required, 37 and 55 indicate the temp. in °C for the sterility assay	Performance	
Date	Preparation Number	Type of Medium	Amount	P F NR 37 55*	Date/Initials	P F NR	Date/Initials
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				☐ ☐ ☐ ☐ ☐		☐ ☐ ☐	
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* For media that was checked for sterility at 55°C, check the box for 55 and place a P or F after it to indicate if the media passed or failed respectively.

Daily Sterilization Record Information Log Form

OPP Microbiology Laboratory

Cycle[1]		Unit Temp.[2]		Max. Thermometer[3]		Chemical Indicator Strips			Items Processed	Sterilization No.[5]	Init.
Type	Time	Min.	Max.	Temp.	Serial #	Lot No.	Exp. Date	Result[4]			

1 Record the cycle as “G” = gravity, “L” = liquid under Type and the duration of the cycle in minutes under Time.
2 Record the maximum and minimum temperature achieved during the sterilize phase of the cycle as indicated by the autoclave printout (Unit).
3 Record the corrected value for the maximum registering thermometer (Max.) and the serial number of the thermometer.
4 Record the results of the chemical indicator strips as “P” for pass or “F” for fail.
5 The Sterilization No. indicates the date as well as the unit location and the run number.